MAY 2 0 2011

APPENDIX B

510(k) SUMMARY - K092801

The 510(k) Summary is submitted per 21 CFR Section 807.92(c)

Submitter's Name: Nimbic Systems, Inc.

Submitter's Address: 4910 Wright Road, Suite 170, Stafford, Texas 77477

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Contact Person: Sean D. Self

Date Prepared: 1 April 2011

Device Trade Name: Air Barrier System

Device Common Name: Air Barrier System or ABS

Device Classification Name: Air Handling Apparatus for Surgical Operating Room

Device Classification: Class II

Summary of Substantial Equivalence: The design, materials, mode of operation and intended use features and performance of the ABS System is substantially equivalent with regard to features and performance of the predicate device, SIBS (K831531).

Device Description: The Air Barrier System (ABS) is used in the surgical operating room. The Air Barrier System (ABS) has two components: a Filter/Blower and an Air Delivery System. The Filter/Blower is non-sterile and reusable. The Air Delivery System is sterile, single-use. The ABS Filter/Blower captures and filters ambient air found in a typical surgical operating room through a High Efficiency Particle Arresting (HEPA) filter. The HEPA filtered air leaves the Filter/Blower via the exit port where it is connected to the Hose portion of the sterile, single-use Air Delivery System. The Hose ends in the Nozzle portion of the Air Delivery System; the Nozzle is gently applied to the incision drape adjacent to a surgical incision. The Nozzle delivers HEPA filtered air directly to the surgical site area to reduce the presence of airborne particulate and microorganisms.

Indications for Use:

The Air Barrier System is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the nozzle and the surface, (2) the incision plane is parallel to the direction of airflow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.

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Technological Characteristics: Comparisons of the ABS System and predicate device show that technological characteristics such as materials, biocompatibility, mode of operation, performance properties, sterilization and packaging are substantially equivalent to the predicate device.

Non-clinical Performance Data: Bench testing included: medical electrical safety, electromagnetic compatibility, sterilization, biocompatibility, microbial precipitation testing, simulated use performance testing, simulated worst-case use performance testing, cadaver surgical procedure testing, maximum air velocity testing in simulated and actual OR settings, turbulence testing at distances from simulated incision sites, and turbulence testing in clinical environment. Results of all bench and cadaver testing demonstrate the safety and effectiveness of the Air Barrier System and its substantial equivalence to the predicate device.

Clinical Performance Data: A clinical study at a single site by a single investigator was conducted to demonstrate the performance characteristics of the Air Barrier System (ABS) during total hip arthroplasty surgery. Twenty-nine (29) patients were randomized into one of three groups: with the ABS active (experiment), with the ABS present but not active (sham), and with no ABS device present (control). Airborne particulate and microorganism samples were collected simultaneously at a discrete single location at the surgical incision within the ABS area of effect and from a discrete single location within the sterile field, but not within the ABS area of effect. The airborne particulate and microorganism samples were taken at ten-minute increments throughout the duration of the surgical procedures. The airborne particulate and microorganism counts observed in the experiment group (with the ABS device active) were significantly lower ($P<0.001$) than that observed in the sham and control groups. In the experiment group, with the ABS device active, the mean microorganism density at the discrete single sampling location within the ABS area of effect was 1.60 colony-forming units per cubic meter compared to 10.73 colony-forming units per cubic meter measured at a discrete single location outside the ABS area of effect. For particulate of size 5µm sampled from single location points throughout each study group, the mean observed particulate density in the experiment group was 524 particles per cubic foot compared with 3853 and 4092 particles per cubic foot in the sham and control groups, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Sean Self
President
Nimbic Systems, LLC
4910 Wright Road, Suite 170
Stafford, Texas 77477

MAY 20 2011

Re: K092801
Trade/Device Name: Air Barrier System (ABS)
Regulation Number: 21 CFR 878.5070
Regulation Name: Air-handing Apparatus for a Surgical Operating Room
Regulatory Class: II
Product Code: ORC
Dated: March 25, 2010
Received: March 26, 2010

Dear Mr. Self:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX A

Indications for Use

510(k) Number (if known): K092801

Device Name: AIR BARRIER SYSTEM (ABS)

Indications For Use:

The Air Barrier System is a portable device for use in a surgical operating room that produces a directed, non-turbulent flow of air to the surgical site. The air flow from the device is HEPA-filtered to reduce the presence of particulate matter and microorganisms at the surgical site during hip arthroplasty. The ABS Nozzle is intended to be used only where: (1) it can be placed on an anatomical surface with no gap between the bottom of the nozzle and the surface, (2) the incision plane is parallel to the direction of airflow, and (3) the incision dimensions are within: 6" (15.2 cm) in width and 20" (50.8 cm) in length. Device effectiveness may not be reliably detectable at a distance of 20 inches from the Nozzle, and effectiveness depreciates beyond this specified area.

Prescription Use ___x_____ Over-The-Counter Use ___

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K092801